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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,557	04/01/2004	Ronald M. Jones	52325-8019.US00	1236

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EXAMINER	
WALLENHORST, MAUREEN	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/816,557	JONES, RONALD M.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *15-22,31 and 34-37* is/are allowed.

6)☒ Claim(s) *1,6,7,9-12 and 23-30* is/are rejected.

7)☒ Claim(s) *4-5, 8, 13-14, 32-33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/25/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 23-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 23-30 now recite that the HDL test pad in the laminate is in simultaneous contact with both a reagent pad and an HDL assay element containing assay reagents effective to produce an indication of HDL cholesterol. However, the specification, as originally filed, does not provide support for a HDL test pad in contact with both a reagent pad and an HDL assay element. The specification only provides support for a HDL test pad in contact with a reagent pad containing a reagent to bind and remove non-HDLs from a sample. The drawings and specification only depict and describe a HDL test pad 64 in contact with a reagent pad 74. There is no third pad or "assay element" also contacting the HDL test pad 64. In addition, the assay reagents effective to produce an indication of HDL cholesterol are only described in the specification as being associated with the HDL pad 64, not with a separate HDL assay element. Therefore, the amendment to independent claim 23 represents new matter.

3. Claims 23-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is indefinite where it recites a HDL test pad having a detectable indicator of HDL cholesterol in simultaneous contact with both a reagent pad and an HDL assay element containing assay reagents effective to produce an indication of HDL cholesterol. It is not understood why both the HDL test pad having a detectable indicator of HDL cholesterol and the HDL assay element containing assay reagents effective to produce an indication of HDL cholesterol concentration are needed since both serve to provide an indication of HDL cholesterol. As noted above, the specification only provides support for the HDL test pad in contact with a reagent pad. However, claim 23 is written in a way that indicates the laminate is comprised of three layers, a reagent pad, the HDL test pad and the HDL assay element.

On line 2 of claim 24, the phrase "said sample reservoir" lacks antecedent basis, and should be changed to recite –said sample collection site--.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 6-7 and 11-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 35 of copending Application No. 10/981,981 (US 2005/0124019). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite an assay device for measuring HDL cholesterol in blood or serum comprising a sample-receiving well or application region, a reagent pad containing a binding reagent effective to selectively bind and remove non-HDLs from a fluid sample, a HDL test pad containing reagents to assay for HDL cholesterol, wherein the reagent pad and HDL test pad are joined together and wherein the reagent pad and HDL test pad can be selectively placed into fluid communication with the sample-receiving sell or application region of the test device. Claim 35 of application serial no. 10/981,981 fails to teach that the HDL test pad and reagent pad are bonded together with either a heat formed bond or an acrylic acid copolymer adhesive bond. However, it would have been obvious to one of ordinary skill in the art to use a conventional type of bond, such as a heat formed bond or an acrylic acid copolymer bond, to adhere the HDL test pad and reagent pad in the method and device recited in the claim 35 of application serial no. 10/981,981 since claim 35 recites that the HDL test pad and reagent pad are laminated together, and laminates are known to be composed of multiple layers of material bonded together with a conventional type of bond such as a heat formed bond or an acrylic acid copolymer bond.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1, 9-10, 23-24, 26 and 28-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29, 31, 33 and

36-42 of copending Application No. 11/109,526 (US 2005/0208609). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite an assay device and method for measuring serum cholesterol associated with high density lipoproteins (HDL) in a blood fluid sample also containing lipoproteins other than HDL such as low density lipoprotein (LDL) and very low density lipoprotein (VLDL) comprising a sample distribution matrix effective to distribute a blood fluid sample from a sample application region to one or more sample collection regions, a HDL test pad in which HDL concentration can be assayed spaced apart from the sample distribution matrix, a reagent pad containing a reagent to selectively bind and remove non-HDLs from the sample, wherein the HDL test pad and reagent pad are joined together or attached to one another, and a mounting means that is effective to maintain the device in a sample distribution position, wherein the HDL test pad and reagent pad are spaced apart from the sample distribution matrix, and to transfer the device to a test position, whereby the HDL test pad and reagent pad are in contact with the matrix. The claims of application serial no. 11/109,526 fail to teach that the HDL test pad and reagent pad are bonded together with either a heat formed bond or an acrylic acid copolymer adhesive bond. However, it would have been obvious to one of ordinary skill in the art to use a conventional type of bond, such as a heat formed bond or an acrylic acid copolymer bond, to adhere the HDL test pad and reagent pad in the method and device recited in the claims of application serial no. 11/109,526, since the claims of application serial no. 11/109,526 recite that the HDL test pad and reagent pad are attached together, and conventional types of bonds such as a heat formed bond or an acrylic acid copolymer bond are known to be used to attach multiple layers of membranes or materials together.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 23-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Jones et al (US 2005/0208609).

Jones et al teach of a high density lipoprotein (HDL) assay device and method for measuring the concentration of HDL-associated cholesterol in a blood fluid sample. The device comprises a main body or support 15, which defines a well 16 sized to receive a quantity of blood. The well is in contact with a sieving pad 22 that is carried in a notched region 20 formed in the upper edge of the support. A capillary conduit 18 may connect the well 16 to the sieving pad 22. Sieving pad 22 functions to partially remove large particulate matter such as blood cells as the sample migrates through the pad matrix in a bottom-to-top direction. The sieving pad 22 in turn contacts an elongate strip or sample distribution matrix 26, which extends along the upper edge of the plate 15. Matrix 26 serves to distribute the sample from a central application region 28, which is in contact with the pad 22, to sample collection regions 30, 32 within the matrix. The device also includes a reaction bar 60 composed of an elongate support 62, and multiple wettable absorbent reaction test pads 64, 66, 68 and 70 carried on the lower surface of the support. Each test pad contains analyte-dependent reagents effective to produce an analyte-

dependent change in the pad. One of the test pads is an HDL test pad 64 that contains reagents that react with HDL so as to detect the HDL. The HDL can be detected optically, or the HDL test pad can be a biosensor that electrochemically measures the production of oxygen or hydrogen peroxide. See paragraph nos. 0072-0076 in Jones et al. Some or all of the test pads are asymmetric membranes having a porosity gradient across the thickness of the membrane. The reaction bar is mounted on a support 15 by mounting means effective to maintain the device in either a sample-distribution position where the test pads and a reagent pad are spaced apart from the sample distribution matrix or a test position, where the test pads and reagent pad are in fluid communication with the sample distribution matrix. The mounting means can be used to break fluid communication between the sample distribution matrix and the test pads after a desired amount of sample has entered the pads or after a predetermined contact time. The mounting means can include a pair of resilient members such as elastomeric blocks 71, 72. Upstream of the HDL test pad is a reagent pad 74 having immobilized therein a polyanionic reagent effective to bind and remove from the fluid sample non-HDL lipoproteins. The reagent pad 74 is located between the sample distribution matrix and the HDL test pad. The reagent pad 74 can be attached to the HDL test pad in permanent contact, as depicted in Figure 1. See paragraph nos. 0050-0065 in Jones et al. The polyanionic reagent in the reagent pad selectively removes LDL and VLDL particles from the fluid sample, and is preferably a sulfonated polysaccharide. The reagent pad 74 effectively traps non-HDL lipoproteins within the pad and prevents them from entering the HDL pad 64. The asymmetric membrane of the reagent pad 74 is preferably oriented with its larger pored surface facing the sample distribution matrix 26, and its smaller pored surface facing and contacting the HDL test pad 64. This orientation allows free access of

sample into the reagent pad through the larger pores, and prevents passage of precipitated material, formed as the sample contacts the precipitating agent in the reagent pad, through the smaller pores. See paragraph no. 0066 in Jones et al. In addition, the asymmetric membrane employed as the HDL test pad is oriented with its smaller pored surface facing upward and its larger pored surface facing reagent pad 74. See paragraph no. 0068 in Jones et al. In one embodiment, the reagent pad 74 consists of a single membrane, but in other embodiments, multiple stacked membranes may be used. See paragraph no. 0067 in Jones et al. The HDL test pad can be formed from a polysulfone membrane impregnated with reagents that detect HDL. The HDL test pad 64 can also be laminated to the reagent pad 74 after the application of reagents. See Figure 3 in Jones et al.

9. Claims 4-5, 8, 13-14 and 32-33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 15-22, 31 and 34-37 are allowable over the prior art of record since none of this prior art of record teaches or fairly suggests a method for preparing a device suitable for measuring serum cholesterol that comprises providing a reagent pad either coated with an acrylic acid copolymer or formed of an asymmetric polysulfone membrane having a small pore side and an open pore side and containing a reagent effective to selectively bind and remove non-HDLs from a fluid sample, applying a HDL test pad containing HDL test reagents therein to the reagent pad, and heating to adhere the reagent pad and the HDL test pad together.

11. Applicant's arguments filed April 25, 2006 have been fully considered but they are not persuasive.

The previous rejections of the claims under the judicially created doctrine of obviousness-type double patenting made in the last Office action mailed on December 29, 2005 are withdrawn in view of the appropriately filed terminal disclaimer received on April 25, 2006. However, new rejections under this statute are set forth above, and a terminal disclaimer over application serial numbers 10/981,981 and 11/109,526 is requested.

The previous rejections of the claims under 35 USC 102 as being anticipated by Anaokar et al, Rittersdorf et al, Kozak et al and Thakore are withdrawn in view of Applicant's persuasive arguments and the amendments made to the claims.

Since new rejections of the pending claims are being made herein, this Office action is not being made final.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

June 16, 2006

Maureen M. Wallenhorst
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